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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,297	08/24/2005	Jonas Angstrom	0933-0232PUS1	6676
2292 7590 03/18/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER BLAND, LAYLA D				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
03/18/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/518,297

Applicant(s)

ANGSTROM ET AL.

Examiner

LAYLA BLAND

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/18/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-92, 94-104 and 106-109 is/are pending in the application.
- 4a) Of the above claim(s) 76-91 and 98-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92, 94-97, 106-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is a response to Applicant's amendment submitted December 18, 2009.

Claims 76-92, 94-104, and 106-109 are pending in this application. Claims 76-91 and 98-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 5, 2007.

Claims 92, 94-97, and 106-109 are examined on the merits herein.

In response to Applicant's query, the drawings are acceptable.

The following rejections of record are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 97, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Finke (CA 2394090, June 14, 2001).

Finke teaches an oligosaccharide composition which approximates to human milk [see abstract]. Human milk oligosaccharides support the normal intestinal flora necessary for function of the gastrointestinal tract and repress pathogenic germs [page

1, lines 26-30] and prevent the adhesion of pathogenic germs and/or substances such as bacteria, toxins, and eukaryotic parasites, the first step of an infection being thereby prevented [page 2, lines 1-9]. Isolation of oligosaccharide fractions can be done using known separation methods [page 5, lines 21-22]. The oligosaccharide mixture can be used as prophylaxis against gastrointestinal infections or for treating of disorders caused by a faulty bacterial or viral colonization of the gastrointestinal tract [page 8, lines 1-13, and claim 8]. The oligosaccharide mixture should contain a neutral fraction and an acidic fraction [page 4, lines 25-28]. Suitable acidic oligosaccharides include 2,3'-sialyl lactose (one elected species) [page 11, Example 4] and suitable neutral oligosaccharides include lacto-N-neo-tetraose (other elected species) [page 11, Example 5]. Finke teaches administration of the claimed oligosaccharides to the claimed patient population (those in need of treatment for gastrointestinal infection). Thus, the claims are anticipated by Finke.

Response to Arguments

Applicant argues that Finke does not anticipate the instant claims because the species are disclosed in two separate examples. This argument has been carefully considered but is not persuasive. Finke teaches administration of a composition comprising an acidic oligosaccharide and a neutral oligosaccharide. The elected species is one of 5 particularly disclosed species of acidic oligosaccharide and one of 2 particularly disclosed species of neutral oligosaccharides. The arrangement required by the claims is the same arrangement taught by Finke (acidic with neutral). Furthermore, Finke's composition could be considered to comprise a genus of acidic and neutral

oligosaccharides. MPEP 2131.02 teaches that one may look to preferred embodiments to determine which compounds can be anticipated. In this case, Finke teaches such a small number of species (10 possible combinations of disclosed species) that the skilled artisan could immediately envisage the combinations. Thus, the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 94-96 and 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finke (CA 2394090, June 14, 2001) in view of Zopf (Lancet Vol 347, April 13, 1996, pp. 1017-1021) or Pickering (Infection 21 (1993) No. 6, pp. 355-357, of record).

Finke teaches administration of an oligosaccharide mixture for treatment of gastrointestinal infection caused by bacterial or viral colonization of the intestinal tract, as set forth above. Finke does not teach specific pathogens or their effects.

Zopf teaches that bacteria for which oligosaccharides have been shown to be prophylactic or therapeutic *in vivo* or are effective antiadhesive agents include *Escherichia coli* and *Helicobacter pylori*, as well as *Salmonella typhimurum* and *Vibrio cholerae* [page 1017, Table]. It is noted that *Escherichia coli* and *Helicobacter pylori* are known to cause diarrhea, as mentioned in the instant specification (page 1).

Pickering teaches that human milk oligosaccharides are protective against *Campylobacter jejuni*, enteropathogenic *E. coli*, and enterotoxigenic *E. coli* [page 355, Table 1].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer Finke's composition to a subject suffering from or at risk for bacterial infections such as those taught by Zopf or Pickering. Finke teaches the treatment of bacterial gastrointestinal infections generally, and Zopf and Pickering teach particular bacteria which are known to be treatable using oligosaccharides. Thus, the skilled artisan could predict that the bacterial infections taught by Zopf or Pickering could be treated using Finke's oligosaccharide composition.

Response to Arguments

Applicant argues that the skilled artisan could arrive at many possible compositions from Finke, and that the skilled artisan would not arrive at the present invention. This argument is not persuasive because Finke discloses only a very limited number of species, as set forth above. The skilled artisan would naturally look to these preferred embodiments.

Applicant argues that the cited references do not teach that which oligosaccharides would be effective against specific organisms. This argument has been carefully considered but is not persuasive. Finke teaches the combination of acidic and neutral oligosaccharides for treatment of disorders caused by bacterial colonization of the gastrointestinal tract, as set forth above, but does not mention specific organisms. However, Zopf teaches that candidates for prevention and/or

therapy of gastrointestinal diseases include carbohydrate receptors recognized by such pathogens as enterotoxigenic *E coli* and *V cholera* [page 1020, Drug Prospects]. Sialylated oligosaccharides containing sialic acid bound to galactose are specifically mentioned with respect to enteropathogenic *E coli* [page 1020, first paragraph]. It is noted that claims 95 and 109 are drawn to treatment of *E. coli* infections and claim 96 is drawn to treatment of *Vibrio* species or wherein the cause of infection is not diagnosed. Although Zopf mentions treatment of some infections caused by organisms not encompassed by the instant claims, Zopf's teachings are not limited to such, as set forth above. Pickering also teaches that oligosaccharides are effective against *E. coli* strains. Although "oligosaccharides" are not one compound but many, as noted by Applicant, Finke teaches preferred combinations of milk oligosaccharides for treatment of gastrointestinal disorders, and Zopf and Pickering teach a number of pathogens which are known to be treated by such. Thus, the skilled artisan would have a reasonable expectation of success. "Obviousness does not require absolute predictability of success." *Id.* at 903, 7"USPQ2d at 1681.

For these reasons, the rejection is maintained.

Conclusion

No claims are allowed.

This application contains claims 76-91 and 98-104, drawn to an invention nonelected with traverse in the reply filed on December 5, 2007. A complete reply to

the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
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